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Docket No.: 50193-109

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of :  
Salah D. KIVLIGHN, et al. :  
Serial No.: 09/892,505 : Group Art Unit: 1636  
Filed: June 28, 2001 : Examiner: NGUYEN, QUANG  
For: TREATMENT FOR CARDIOVASCULAR DISEASE

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APR 30 2003

**RESPONSE TO OFFICIAL ACTION**

TECH CENTER 1600/2900

Commissioner for Patents  
Washington, DC 20231

Sir:

This is in response to the Official Action dated January 29, 2003 in this application. Reconsideration of the application is requested in view of the following remarks and accompanying evidence.

It is noted that the restriction requirement has been made final and that claims 3, 4, 6 and 8-13 stand withdrawn from further consideration as drawn to a non-elected invention. Applicant is retaining these claims in the application pursuant to filing a Divisional application directed thereto in due course. If the Examiner should find this application to be in condition for allowance as a result of this response, the Examiner is authorized to cancel the non-elected claims 3, 4, 6 and 8-13 from the application.

It is noted that the Examiner has acknowledged the filing of an Information Disclosure Statement which was filed on November 20, 2002. However, there does not appear to be any acknowledgement of an Information Disclosure Statement filed June 5,

2002 to present copies of prior art from the International Search in the corresponding PCT application. Therefore, for the Examiner's convenience, enclosed is one complete copy of the Information Disclosure Statement filed June 5, 2002 which presents copies of prior art developed in the International Search by the European Patent Office in the corresponding PCT application U.S. 01/20457. Included with this copy of the Information Disclosure Statement is a copy of Applicant's return card evidencing the date of filing of June 5, 2002. Therefore, no fees are required and it is requested that this Information Disclosure Statement be fully considered.

In the Official Action, elected claims 1, 2, 5 and 7 are rejected as obvious and unpatentable over Mentrup et al. U.S. Patent 4,539,323. The Examiner holds that Mentrup et al., at column 9, lines 7-30, disclose the use of allopurinol, one of Applicant's active agents, as being known to treat hypertension. The Examiner concludes that this reference would have motivated one of ordinary skill in the art to use Applicant's claimed active agent to treat hypertension since the reference teaches the use of the claimed activate agent in combination with agents which treat hypertension. This rejection is respectfully traversed and reconsideration is requested.

As correctly noted by the Examiner, Applicant's main claim 1 is directed to a method of treating hypertension comprising administering a therapeutically effective amount of an agent or pharmaceutically acceptable salt thereof which is capable of reducing uric acid levels in a patient in need of such treatment. As indicated in claim 7, allopurinol is an active agent suitable for this purpose. Applicant submits, however, that the Mentrup et al. reference neither teaches nor suggests the invention claimed in claims 1, 2, 5 and 7.

Mentrup et al. disclose piperidine compounds which are indicated as active as vasodilators and hypotensives. The patent discloses in column 8 that the piperidine compounds of the patent have a long lasting hypotensive effective. In column 9, the patentee discloses that the piperidine compounds of the patent can be combined with one or more other pharmaceutical substances such as substances having a cardiac/circulatory effect or a hypotensive effect. There are also mentioned diuretics, beta blockers, vasodilators, sympathicolitics and converting enzyme blockers. Thereafter follows a table which lists 34 separate materials which are apparently suitable for combination with the piperidine compounds of this patent. One material listed is allopurinol but there is no indication in this table as to the therapeutic effect of the particular substances listed.

In the Official Action, the Examiner suggests the Mentrup et al. disclose the use of allopurinol as being known to treat hypertension. Applicant submits that this conclusion is not supported by Mentrup et al. In fact, to Applicant's knowledge, allopurinol is not known to treat hypertension and certainly is not disclosed in column 9 of Mentrup et al. as being a material useful to treat hypertension. Further, as shown in the enclosed copy of *Merck Index*, 13th Edition, 2001, pages 52 and 53, allopurinol is known for the treatment of hyperuricemia and for the treatment of chronic gout. Therefore, the Merck Index is evidence which rebuts the Examiner's presumption that allopurinol is known to treat hypertension.

Further, the Official Action is inconsistent. At page 3 of the action, second full paragraph, the Examiner states the Mentrup et al. at column 9, lines 7-30, disclose the use of allopurinol, one of Applicant's active agents, as being known to treat hypertension. In the next paragraph, the Examiner states that the reference differs from Applicant's claims,

specifically claim 7, since it fails to teach that allopurinol has a hypotensive effect. Applicant agrees that Mentrup et al. do not disclose that allopurinol is known to treat hypertension. However, Applicant disagrees with the Examiner's statement that the reference would have motivated one of ordinary skill in the art to use Applicant's claimed active agent to treat hypertension because it teaches the use of the claimed active agent in combination with agents which treat hypertension. This is not believed to be what is taught by Mentrup et al. Applicants submit that what Mentrup et al. teach in column 9 is that the hypotensive agents of his patent can be used with other therapeutic agents which can be hypotensive but can also have therapeutic activity other than as hypotensives. Applicant submits that the teaching from the Merck Index presented herewith rebuts any presumption that allopurinol is known to be a hypertensive agent and rebuts the assumption made that the reference provides motivation to one of ordinary skill to use allopurinol as a hypotensive agent. In fact, since the Merck Index discloses that allopurinol is known for the treatment of hyperuricemia, a condition in which a patient's circulating blood contains elevated levels of uric acid, allopurinol falls within the substances which have a cardiac/circulatory effect as described by Mentrup et al. at column 9, line 10. This is further evidence that allopurinol is not disclosed or suggested by Mentrup et al. as a hypertensive agent.

For these reasons, it is submitted that the reference relied on by the Examiner neither teaches nor suggests the invention claimed in claims 1, 2, 5 and 7 and the rejection should be withdrawn.

It is believed that the above-represents a complete response to the Official Action and serves to place this application in condition for allowance.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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